K070974

MAY 24 2007

## ATTACHMENT 4

### 510(k) SUMMARY
### Light Relief Infrared Lamp

This 510(k) summary is being submitted in accordance with 21 CFR 807.92

**1. Submitter's Information**

| | |
|---|---|
| Name: | Light Relief, LLC |
| Address: | 4929 Wilshire Blvd., Ste. 500<br>Los Angeles, CA 90010<br>Phone: (323) 202-1500<br>Fax: (323) 938-9200 |
| Contact: | Laurie McLaughlin<br>Counsel for Light Relief, LLC |
| Date Prepared: | March 23, 2007 |

**2. Device Information**

| | |
|---|---|
| Trade/Proprietary Name: | Light Relief Pain Relief Device |
| Common/Usual Name: | Infrared Lamp |
| Classification Name: | Infrared Lamp, Therapeutic Heating<br>(21 CFR 890.5500) |
| Product Code: | ILY |

**3. Predicate Device**

Light Relief (K993686), originally named Light Patch
Purchased from Bioscan, Inc. by Light Relief, LLC

**4. Intended Use**

The Light Relief Infrared Lamp is an over-the-counter device intended for use wherever hot applications are desirable for personal comfort and whenever recommended by a licensed medical professional for the purpose of providing temporary relief of minor aches and pains in muscles and joints.

## 5. Device Description

The Light Relief Infrared Lamp is a pain relief device consisting of a hand-held module with a flexible pad, containing an array of 59 colored and infrared LED's, and a power supply. Minor design changes have been made to the device, including: an increase in the pad size and number of LEDs; addition of rechargeable battery option, automatic shut off feature, internal heating element and frequency options; and changes to the pad material, pad attachment method and body strap closure method. These modifications do not change the indications for use or raise any new issues of safety or efficacy. Details are provided in the Device Description Section of this submission.

## 6. Substantial Equivalence

The modified Light Relief Infrared Lamp is substantially equivalent to the unmodified device. The data in this 510(k) notification demonstrate that the Light Relief device shares the same intended use, and similar design features and functional features and is therefore substantially equivalent to the unmodified device. The changes to the device do not affect the indications for use or raise new issues of safety or efficacy. Details are provided in the Substantial Equivalence Section of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 24 2007

Light Relief, LLC
% Ms. Laurie McLaughlin
Counsel
4929 Wilshire Boulevard
Suite 500
Los Angeles, California 90010

Re: K070974
Trade/Device Name: Light Relief
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: May 7, 2007
Received: May 11, 2007

Dear Ms. McLaughlin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## ATTACHMENT 2

### Indications for Use

**510(k) Number (if known):**

**Device Name:** Light Relief

**Indications for Use:**

This infrared heat lamp is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating and/or maintaining tissue temperature.

- Use wherever heat application is prescribed for personal comfort and the temporary relief of minor muscular pain, joint pain and stiffness.
- Provides temporary relief of minor aches and pains in muscles and joints.
- Aids in the relaxation of muscles.
- Helps provide a temporary improved range and freedom of motion due to muscle relaxation and temporary minor pain relief.
- Provides a temporary increase in local blood circulation.

Prescription Use_____ AND/OR Over-the-Counter Use___X___
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070974

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number_____